# Congress of the United States

Washington, DC 20510

February 10, 2006

Andrew C. von Eschenbach, M.D.
Acting Commissioner of Food and Drugs
5600 Fishers Lane
Rockville, MD 20854

Dear Dr. von Eschenbach:

We write today to urge that you issue the guidance documents we understand the Food and Drug Administration (FDA) has already drafted that would clarify the approval requirements for generic versions of insulin and human growth hormone (HGH).

Since the passage of the Drug Price Competition and Patent Term Restoration Act of 1984, consumers have saved tens of billions of dollars due to the availability of lower-cost generic drugs. Over the past two decades, there has also been a dramatic increase in the number of biological products on the market, including therapeutic products that are made from living organisms, recombinant DNA, genetic engineering, and cell therapy. The development of generic alternatives for biological products could be an important factor in controlling health care costs and in making important new therapies more widely available.

On numerous occasions, officials at your agency have indicated to us that they are considering the issues necessary to move toward a system of approval for generic biological products. We recognize that there are important scientific and legal issues that must be worked through as a part of this process, including establishing the proper criteria for demonstrating equivalence, and for many products, determining whether there is adequate legal authority for you to approve generic versions of drugs regulated under the Public Health Service Act (PHS Act). It is clear that resolving these issues may take some time.

That being said, we believe the resolution of these issues for biological products should not delay action that would permit the marketing of generic versions of insulin and human growth hormone. In 2002, FDA officials drafted guidance documents providing the requirements for approval of generic forms of insulin and HGH. Since that time, the Agency has held public workshops and public meetings on various issues pertaining to generic biologics, but it apparently decided to defer the release of the guidance documents for insulin and HGH until it had resolved issues pertaining to the entire class of biologics.

Now, several years later, the effort to develop the appropriate regulatory requirements for generic biologics appears to be at a complete standstill. This was underscored just last month, when the Biotechnology Industry Organization cancelled a panel discussion on the generic biologics issue at its annual meeting, noting that "[t]he movement toward follow-on biologics in

the United States appears to have slowed, if not stalled . . . FDA has not published a guidance following the public workshops it sponsored in September 2004 and March 2005."[1]

The time has come for FDA to issue the guidance documents on the approval requirements for insulin and HGH. It is our strong belief that Insulin and HGH are two products that should be separated from the development of a larger regulatory framework because they do not raise the same scientific and regulatory issues as biological products. They have relatively simple structures with a long history of safe use by millions of people, as recognized by the FDA staff that have drafted guidance documents on establishing the equivalence of generic versions of those products. Indeed, FDA has offered no scientific reasons for delaying the issuance of the guidance documents.

Moreover, because both of these products currently are regulated under the Federal Food, Drug, and Cosmetic Act, establishing the approval requirements for their generic forms does not raise the legal issues that exist with approval of generic forms of products regulated under the PHS Act. The legal framework for such approval already exists. It is time for FDA to clarify what data it will require that manufacturers provide when seeking to market a generic insulin or HGH product.

The Agency may recognize all of the points noted above because FDA officials repeatedly have made them when announcing that these documents would be forthcoming. FDA can continue to wrestle with the separate issues raised by the development of a regulatory framework for more complicated products regulated under the PHS Act. There simply is no excuse -- scientific, legal, or otherwise -- for FDA to continue to delay the release of these guidance documents.

We say with some pride that the 1984 Act, which we authored, has been an extraordinary success with regard to traditional chemical drugs. Now it is time for FDA to take the small but critical next step of issuing the guidance documents it already has developed on the approval requirements for generic insulin and HGH.

Sincerely,

Henry A. Waxman
Member of Congress

Orrin G. Hatch
United States Senator

[1] *BIO Cancels Biogenerics Session for Annual Meeting in Chicago*, FDA WEEK, January 13, 2006.